REMARKS

Entry of the above amendments and reconsideration and withdrawal of the rejection of claims 73 to 86 and 90 to 108 is respectfully requested. Claims 76, 78 and 102 to 106 were cancelled. Claims 37 to 41, 44 to 72, and 87 to 89 were withdrawn. Claims 73, 77, 79, 107, and 108 were amended. Support for the amendments to Claim 73 may be found in the specification at page 4, lines 1-6; page 9, lines 6-8. Claims 77 and 79 were amended to change claim dependency from claim 37 to claim 73 since claim 37 is now withdrawn. Claims 107 and 108 were amended to replace the trademark/trade name of Eudragit 4135F, Klucel EF, Klucel JF, and Klucel GF with their definitions as defined in the Manufacturer's data sheet and on page 7, lines 8-13 of the specification. Applicants reserve the right to file any subsequent application on cancelled subject matter.

1. Claims 73-86 and 90-108 are rejected 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

The Examiner states that the claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Particularly, the Examiner states that while the present specification at page 6, lines 9-10 discloses that Eudragit 4135F has an *average* molecular weight of about 220,000, the specification does not appear to provide support for the "molecular weight of about 220,00[0]" recited in line 10 of claim 73.

In response, Applicants have amended claim 73 to replace "molecular weight of about 220,00" with "molecular weight of about 220,000."

The Examiner further states that claim 73 recites the phrase "each sub-unit being selected from" in line 2 and that this phrase is confusing because it is not entirely clear if each of the sub-unit is comprised of both (a) and (b), or (a) or (b) in an alternative manner.

This rejection is moot in light of the amendment to claim 73, where claim 73 was amended to include the word "and" in line 26 to reflect that each of the sub-unit is comprised of both (a) and (b).

The Examiner further states that claim 73 is rejected because it is not entirely clear whether components (i) through (vi) are required altogether or alternatively.

This rejection is moot in light of the amendment to claim 73, where claim 73 was amended to include the word "and" in line 20 to reflect that the components (i) through (vi) are required altogether.

The Examiner further states that claim 73 recites the limitation "wherein the shell material between and including the inner and outer surfaces" in lines 24-25 and there is insufficient antecedent basis for this limitation in the claim.

This rejection is moot in light of the amendment to claim 73 in lines 7-8, where claim 73 was amended to include the language "wherein the shell is composed of a shell material" to provide antecedent basis for the shell material.

The Examiner further states that claim 73 recites the limitation "release of the drug substance contained in the solid matrix" in line 31 and there is insufficient antecedent basis for this limitation in the claim.

This rejection is moot in light of the amendment to claim 73 in lines 40-41, where claim 73 was amended to replace "the solid matrix" with "a solid matrix."

The Examiner states that claims 107 and 108 contain the trademark/trade name Eudragit 4135F, Klucel EF, Klucel JF, and Klucel GF and where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph.

In response, in claims 107 and 108, the Applicants have amended the term "Eudragit 4135F" to the term "copolymer of methyl acrylate, methyl methacrylate and methacrylic acid, with a molecular weight of about 220,000 and a ratio of free carboxyl groups to ester groups of 1:10." The Applicants have amended the term "Klucel EF" to the term "hydroxypropylcellulose polymer with an average molecular weight of 80,000 having a solution viscosity of 300-600 mPas when dissolved in 10 weight % in water at 25°C." The Applicants have amended the term "Klucel JF" to the term "hydroxypropylcellulose polymer with an average molecular weight of 140,000 having a solution viscosity of 150-400 mPas in 5 weight % in water at 25°C." The Applicants have amended the term "Klucel GF" to the term "hydroxypropylcellulose polymer with an average molecular weight of 370,000 having a solution viscosity of 150-400 mPas in 2 weight % in water at 25°C." Support for these terms are found in the specification on page 7, lines 8-13 and the Manufacturer's data sheet, a copy of which accompanies this response.

2. Claims 73 to 86 and 90 to 108 are rejected under 35 U.S.C. 103(a) as being unpatentable over McAllister et al. US2003/0049311, in view of Nishioka et al. US 5,861,173 or Gidwani et al. US6,270,797 or Li et al. US 7,476,403.

3. Claims 73 to 86 and 90 to 108 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown et al. WO02/060384A2, in view of Nishioka et al. US 5,861,173 or Gidwani et al. US6,270,797 or Li et al. US 7,476,403.

The USPTO provided guidelines regarding obviousness rejections following the decision of *KSR Int'l Co. v. Teleflex, Inc.*, 127 S. Ct. 1727 (2007):

> Obviousness is a question of law based on underlying factual inquiries. The factual inquiries enunciated by the Court [in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966)] are as follows:
>
> (1) Determining the scope and content of the prior art;
> (2) Ascertaining the differences between the claimed invention and the prior art; and
> (3) Resolving the level of ordinary skill in the pertinent art.
>
> Objective evidence relevant to the issue of obviousness must be evaluated by Office personnel. . . The question of obviousness must be resolved on the basis of these factual determinations. While each case is different and must be decided on its own facts, the *Graham* factors, including secondary considerations when present, are the controlling inquiries in any obviousness analysis. . .
>
> In short, the focus when making a determination of obviousness should be on what a person of ordinary skill in the pertinent art would have known at the time of the invention, and on what such a person would have reasonably expected to have been able to do in view of that knowledge. This is so regardless of whether the source of that knowledge and ability was documentary prior art, general knowledge in the art, or common sense. . .
>
> Once the *Graham* factual inquiries are resolved, Office personnel must determine whether the claimed invention would have been obvious to one of ordinary skill in the art. . .
>
> The key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. The Supreme Court in *KSR* noted that the analysis supporting a rejection under 35 U.S.C. 103 should be made explicit. The Court quoting *In re Kahn*, stated that "'[R]ejections on obviousness cannot be sustained by mere

conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.

Federal Register, Vol. 72, No. 195, 10/10/2007, pages 57526-575289.

To maintain objectivity, reference to MPEP 2141.01(a), Section I is warranted:

The examiner must determine what is 'analogous prior art' for the purpose of analyzing the obviousness of the subject matter at issue. 'In order to rely on a reference as a basis for rejection of an applicant's invention, the reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the inventor was concerned.' *In re Oetiker*, 977 F.2d 1443, 1446, 24 USPQ2d 1443, 1445 (Fed. Cir. 1992).

A prerequisite to making this [obviousness] finding is determining what is 'prior art,' in order to consider whether 'the differences between the subject matter sought to be patented and the prior art are such that **the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art**.' 35 U.S.C Section 103. Although Section 103 does not, by its terms, define the 'art to which [the] subject matter [sought to be patented] pertains,' this determination is frequently couched in terms of whether the art is analogous or not, i.e. , whether the art is 'too remote to be treated as prior art.' *In re Sovish*, 769 F.2d 738, 741, 226 USPQ 771, 773 (Fed.Cir. 1985). [*In re Clay*, 966 F.2d 656; 23 USPQ2d 1058, 1060 (Fed. Cir. 1992), emphasis added.]

In *Clay*, the invention was a process for storing refined liquid hydrocarbon product in a storage tank having a dead volume between the tank bottom and its outlet port. Two prior art references were cited. The court determined that the references were not within the same field and that the references were not proper because the problems to be solved were not reasonably pertinent to the problem of Clay's invention:

Even though the art disclosed in [the] Sydansk [reference] is not within Clay's field of endeavor, the reference may still properly be combined with Hetherington if it is reasonably pertinent to the problem Clay attempts to solve. *In re Wood*, 599 F.2d at 1036, 202 USPQ at 174. A reference is reasonably pertinent if, even though it may be in a different field from that of the inventor's endeavor, it is one which, because of the matter with which it deals, logically would have commended itself to an inventor's attention in considering his problem. **Thus, the purposes of both the invention and the prior art are important in determining whether the reference is reasonably pertinent to the problem the invention attempts to solve.** If a reference disclosure has the same purpose as the claimed invention, the reference relates to the same problem, and that fact supports use of that reference in an obviousness rejection. An

inventor may well have been motivated to consider the reference when making his invention. If it is directed to a different purpose, the inventor would accordingly have had less motivation or occasion to consider it.

MPEP 2141.01(a) at pages 1060-1061.

Applicants also direct attention to the MPEP states at 2143.01.IV:

A statement that modifications of the prior art to meet the claimed invention would have been 'well within the ordinary skill of the art at the time the claimed invention was made' because the references relied upon teach that all aspects of the claimed invention were individually known in the art is not sufficient to establish a *prima facie* case of obviousness without some objective reason to combine the teachings of the references. *Ex parte Levengood*, 28 USPQ2d 1300 (Bd. Pat. App. & Inter. 1993). . .

>[R]ejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.'" *KSR*, 550 U.S. at ___, 82 USPQ2d at 1396 quoting *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006). . .

The prior art can be modified or combined to reject claims as *prima facie* obvious as long as there is a reasonable expectation of success. . . Obviousness does not require absolute predictability, however, **at least some degree of predictability is required**. Evidence showing there was no reasonable expectation of success may support a conclusion of nonobviousness.

MPEP 2143.01 IV at pages 2100-2140.

The rejection is respectfully traversed for the reasons set forth in detail below.

First, Applicants object to the use of McAllister, Brown, Nishioka, Gidwani, and Li as prior art for claims 73 to 75, 77, 79 to 86, 90 to 101, 107, and 108. McAllister and Brown concern the field of powder tableting and cannot be compared to the extrusion and injection molding process. Nishioka, Gidwani, and Li concern conventional tablet technology that use standard pharmaceutical blended API. This technology is developed to be specific for the API being used. Nishioka, Gidwani, and Li appear to address the problem of delivering a control release formulation of a drug that is sparingly soluble or insoluble. However, Applicants' invention relates to

polymeric composition uncoupled from the API. The API release rate is independent of the constituents of molded capsule. McAllister, Brown, Nishioka, Gidwani, and Li concerns different technologies for solving different problems, and therefore, should be found to be non-analogous art.

To further highlight the differences to Nishioka, Gidwani, and Li, Applicants have amended Claim 73 to recite that each sub-unit is extruded and injection moulded and provides for a pulsatile release, which Nishioka, Gidwani, and Li do not disclose. In addition, Applicants have amended the HPC blend in claim 73 to comprise Klucel EF and Klucel JF or Klucel EF and Klucel GF, which are not disclosed in combination in Nishioka, Gidwani, or Li.

Second, nothing has been presented to show reasonable expectation of success when the prior art is combined. In light of the amendments to claim 73, where the HPC blend is now amended to reflect Klucel EF and JF, or Klucel EF and Klucel GF, even if one of ordinary skill had considered the prior art references used by the Examiner, the references would not suggest these specific blends. Nishioka discloses HPC-L, HPC-M and HPC-H with molecular weights of 140K, 620K and 910K respectively. (Nishioka: Col. 2, lines 34-50). See attached Nisso HPC brochure. Gidwani discloses only Klucel EF and LF. (Gidwani: col. 4, lines 1-9; col. 8, lines 8-36). Li also discloses Klucel EF and LF only. (Li: Col. 10, lines 56-58). By contrast, in Applicants' application examples 1, 2, 7, and 8 show that by using the two specific HPC blends that Applicants seek to claim, EF and JF or EF and GF, these particular blends appear to be the best HPC blend combination. Using these two specific blends, the shells of 0.5 mm wall section can be manufactured without problems during the extrusion and injection molding process. At worst, some small cracks appear in example 8, but the test is particularly stressful when using a 0.3 mm wall section, which is the thinnest possible wall section. (Applicants' application: pg. 18, lines 1-35; pg. 19, lines 1-4; pg. 20, lines 6-18; pg. 21, lines 1-6). In Applicants' application examples 4, 5, and 6 show by contrast that using other HPC blends is not as ideal as using an EF and JF or EF and GF blend, where incomplete filling of the mould occurred. (Applicants' application: pg. 19, lines 6-16; pg. 20, lines 1-3). By using the blends indentified in the prior art, one of ordinary skill would have found solutions that are technically inferior to those claimed. At best, one of ordinary skill could have conceived of a blend of EF and LF, since neither McAllister nor Brown mentions Klucel GF or JF.

Based on the arguments above, Applicants respectfully request that the Examiner remove his rejection on this ground. Accordingly, Applicant respectfully requests that the Examiner reconsider and withdraw the 35 U.S.C. § 103(a) rejection of claims 73 to 75, 77, 79 to 86, 90 to 101, 107, and 108.

CONCLUSION

Applicant respectfully requests reconsideration of the rejection of the above-mentioned claims and request an early and favorable allowance.

Respectfully submitted,

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